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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,246	02/26/2002	Jeffrey George Jones	1133/2002	6437
29933	7590	07/26/2004		
PALMER & DODGE, LLP			EXAMINER	
KATHLEEN M. WILLIAMS			HORLICK, KENNETH R	
111 HUNTINGTON AVENUE				
BOSTON, MA 02199			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,246	JONES ET AL.	
	Examiner	Art Unit	
	Kenneth R Horlick	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 26 February 2002 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/21/2002</u> (3 pages) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

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1. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are confusing because of the step "generating duplexes in said amplified products" in independent claims 1 and 14. The amplified products created in the previous step are already in duplex form; thus, it cannot be understood how one is to "generate duplexes in said amplified products" when said products already are duplexes. Clarification is required. It would appear that the claims intend the steps of denaturing the amplified products, and then allowing the denatured products to gradually re-form duplexes.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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3. Claims 1, 2, 4, 7-14, 16, 17, 19, and 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by either of Watnick et al. (1997) or Turco et al. (1995).

These claims are drawn to methods of mutation analysis of polycystic kidney disease nucleic acids, comprising amplifying a nucleic acid using two primers which bind to SEQ ID NO:1 or 2, subjecting amplification products to heteroduplex analysis, and detecting any heteroduplex as an indication of the presence of a mutation.

Watnick et al. teach such a method; see abstract and "Materials and Methods" on pages 1479-1480. This reference also teaches the use of nested amplification (second column and Fig. 4 on page 1475) and restriction digestion using, for example, Pst I (Fig. 3 on page 1475).

Turco et al. also teach such a method; see abstract and "Materials and Methods" on page 1334.

4. Claims 1, 2, 4, 6-17, 19, and 21-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Germino et al. (US 2003/0008288).

Germino et al. disclose the claimed methods; see paragraphs [0012]-[0032], [0040]-[0066], [0124]-[0129], [0146]-[0152].

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Watnick et al. or Turco et al. in view of Liu et al.

These claims are drawn to the methods as described above, further wherein detection of heteroduplexes is by the technique of DHPLC.

The teachings of Watnick et al. and Turco et al. are described above.

These references do not teach DHPLC.

Liu et al. teach that the technique of DHPLC is an advantageous means of detecting mutations and polymorphisms (see abstract and introduction on pages 1396-1397, and final paragraph bridging pages 1399 and 1400).

One of ordinary skill in the art would have been motivated to modify the method of either of Watnick et al. or Turco et al. by using DHPLC as the means of detecting heteroduplexes because Liu et al. taught that DHPLC was a reliable and sensitive means for heteroduplex detection. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

6. Claims 3, 5, 18, and 20 contain allowable subject matter. No prior art has been found teaching or suggesting the use of a primer corresponding to any of SEQ ID NO:3-49 in heteroduplex analysis of polycystic kidney disease nucleic acids as set forth in either SEQ ID NO:1 or 2. No claims are allowable.
7. Harris et al. (US 6,485,960) and Reeders et al. (US 5,891,628) are made of record as references of interest.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kenneth R Horlick
Primary Examiner
Art Unit 1637

06/16/04